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TO THE UNITED STATES PATENT OFFICE**Applicants Docket Number:
ST98008 US PCTApplicants:
CIOLINA, et al.Serial No.
09/646,399Filing Date:
November 1, 2000Title of Invention:
VECTORS FOR TRANSFERRING NUCLEIC ACIDS, COMPOSITIONS CONTAINING THEM AND THEIR USES**CERTIFICATE OF TRANSMISSION**I hereby certify that this correspondence is being transmitted via facsimile to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, Daniel M. Sullivan, at 703-872-9306, onDate of Deposit August 31, 2004Printed Name of Person Signing Certificate Jonas Pierre, Sr.

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Total Number of Pages Sent: **6**Attorney: **Joel B. German**Reg. No. **48,676**Group Art Unit: **1636**Examiner: **SULLIVAN, Daniel M.**TO: Mail Stop Patent Application
Commissioner for Patents
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- ☒ Reply to Restriction Requirement
- ☒ Response to Finding Lack of Unity of Invention Under 37 CFR § 1.475 - Transmittal (4 pages)
- ☒ Extension of Time Petition (1 page)
- ☐ Issue Fee Transmittal & Advance Order
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Aventis Pharmaceuticals Inc. template (March 2001)

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NO. 6968 P. 3

AUG 31 2004

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of
CIOLINA ET AL.

Examiner: **SULLIVAN, Daniel M.**

Serial No.: **09/646,399**

Art Unit: **1636**

Filed: **November 1, 2000**

Title: **VECTORS FOR TRANSFERRING
NUCLEIC ACIDS, COMPOSITIONS
CONTAINING THEM AND THEIR
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**RESPONSE TO FINDING OF LACK OF UNITY
OF INVENTION UNDER 37 CFR § 1.475**

Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the finding of lack of unity of invention under 37 CFR § 1.475 mailed June 3, 2004, the time to respond to which has been extended two months to September 3, 2004 by the accompanying petition, the Applicants provisionally elect the claims of Group I (claims 1-9, 14-37), the intracellular targeting signal of claim 23, the cationic lipid of claim 29, and the neutral lipid of claim 31. The Applicants respectfully disagree with the finding of lack of unity. They request that the Examiner reconsider and modify it in view of the remarks below.

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Remarks

The Examiner has required that the Applicants elect one of the following groups of claims:

- Group I, claims 1-9 and 14-37, directed to a vector comprising a double-stranded DNA molecule and at least one oligonucleotide coupled to a targeting signal capable of forming a triple helix with a specific sequence present on the DNA, wherein the specific sequence is poly-GAAA and the oligonucleotide comprises poly CTT;
- Group II, claims 1-7, 10 and 14-37, wherein the specific sequence comprises SEQ ID NO: 3;
- Group III, claims 1-7, 11 and 14-37, wherein the specific sequence comprises SEQ ID NO: 6;
- Group IV, claims 1-7, 12 and 14-37, wherein the specific sequence comprises SEQ ID NO: 8;
- Group V, claims 1-7, 12 and 14-37, wherein the specific sequence comprises SEQ ID NO: 10;
- Group VI, claims 1-7, 13-37, wherein the specific sequence comprises SEQ ID NO: 9;
- Group VII, claim 38, directed to the use of the vector of Groups I-VI for the manufacture of a medicament;
- Group VIII, claim 39, directed to a method of transfecting nucleic acids;
- Group IX, claim 40, directed to a method of treating diseases; and
- Group X, claims 41 and 42, directed to a recombinant cell containing the vector of Groups I-VI.

The Examiner further restricted Groups I-VI to a single targeting signal recited in claims 21, 25, a single transfecting agent recited in claims 28 and 29, and a single adjuvant recited in claims 30, and 33.

The Examiner found that there is no unity of invention because, according to the Examiner, the inventions these claims define are not linked by a special technical feature; that is, not linked by a feature that defines a contribution over the prior art. See 37 C.F.R. § 1.475. The reference the Examiner relies on is Felgner *et al.*

First, the Applicants note that the European Patent Office, which conducted the international search and the international preliminary examination, applied the same unity of invention rules and found no fault with respect to unity of invention.

Second, there are fundamental differences between the vector of Felgner *et al.* and the vector of the Applicants. The Examiner states that the technical feature shared by Groups I-X is a vector comprising a double-stranded DNA molecule and at least one oligonucleotide coupled to a targeting signal and capable of forming a triple helix with a specific sequence present in the double-stranded DNA molecule. According to the Examiner, Felgner *et al.* teaches a vector comprising a double-stranded DNA molecule and at least one oligonucleotide coupled to a targeting signal and capable of forming a triple helix with a specific sequence present in the double-stranded DNA molecule. The Applicants respectfully disagree.

Felgner *et al.* describes PNA clamps which have two identical PNA sequences joined by a flexible hairpin linker containing three 8-amino-3,6-dioxaoctanoic acid units; when a PNA clamp is mixed with a complementary homopurine homopyrimidine DNA target sequence, a PNA-DNA-PNA triplex hybrid can form. Felgner *et al.* does not describe a double-stranded DNA molecule and at least one oligonucleotide coupled to a targeting signal and capable of forming a triple helix with a specific sequence present in the double-stranded DNA molecule. The PNA described by Felgner *et al.* form a PNA-DNA-PNA triplex because of the hairpin formed by the PNA. The triplex includes only a single strand of the DNA (see figures 3 and 7).

In contrast with the present invention, the PNA describe by Felgner *et al.* do not form a triple helix with the double-stranded DNA molecule and therefore do not anticipate the general technical feature of a vector comprising a double-stranded DNA molecule and at least one oligonucleotide coupled to a targeting signal and capable of forming a triple helix with a specific sequence present in the double-stranded DNA molecule. The present invention is a completely different one.

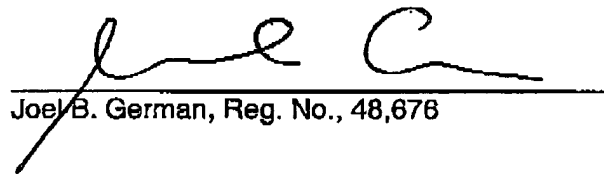
In view of the foregoing, the Applicants respectfully request that the Examiner withdraw the finding of lack of unity.

The Examiner further required that the Applicants elect a single species of targeting signal, transfecting agent, and adjuvant from claims 21-25, 28-29, and 30-33. The Applicants respectfully submit that such a requirement is improper. Where related species are recited in the same claim, there is unity of invention as long as

the species are of the same nature. M.P.E.P. § 1850(D). The claims recite species of the same nature, dividing targeting signals, transfecting agents, adjuvants between separate claims; it is not as though a single claim recites all three. The Applicants therefore respectfully request that the Examiner withdraw the lack of unity finding with respect to the species recited in claims 21-25, 28-29, and 30-33.

Should the Examiner believe that an interview would advance the prosecution of this application, the Applicants invite him to contact the undersigned at 908.231.3444.

Respectfully submitted,



Joel B. German, Reg. No., 48,678

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